IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
RADIUS HEALTH, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") files this Complaint for patent infringement against Radius Health, Inc. ("Radius") under 35 U.S.C. § 271 concerning Radius's Supplemental Submission to New Drug Application No. 208743.

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 7,517,334 ("the '334 patent"). This action relates to Radius's Supplemental Submission to New Drug Application ("NDA") No. 208743 filed under 21 U.S.C. § 355(b)(2) by Radius to the U.S. Food and Drug Administration ("FDA") for Tymlos® (abaloparatide). Upon information and belief, the FDA views Radius's Supplemental NDA Submission as covered by Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), thereby constituting an act of infringement under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

THE PARTIES

2. Lilly is a corporation organized and existing under the laws of Indiana with its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of innovative pharmaceutical products throughout the world.

3. Radius is a corporation organized and existing under the laws of Delaware with its corporate offices and principal place of business at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210.

4. On information and belief, Radius is a biopharmaceutical company that develops endocrine therapeutics and commercializes those therapeutics in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, including 35 U.S.C. § 271.

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this judicial district under 28 U.S.C. § 1400(b) because Radius resides in this District.

8. This Court has personal jurisdiction over Radius because it is a Delaware corporation and is "at home" in this District. Further, Radius regularly does or solicits business, or engages in a persistent course of conduct in this District, or derives substantial revenue from things used or consumed in this District.

9. On information and belief, Radius maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over Radius. On information and belief, Radius directly, or indirectly, develops, manufactures, markets, and sells pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Radius derives substantial revenue from Delaware drug sales, including the sale of Tymlos® (abaloparatide), and has availed itself of the privilege of doing business within the State of Delaware. Exercising jurisdiction over Radius is therefore reasonable and fair.

FACTUAL BACKGROUND

A. Forteo®

10. Lilly is the holder of approved NDA No. 021318 for the manufacture and sale of teriparatide [rDNA origin] injection, approved by the FDA for: (1) treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy; (2) increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy; and (3) treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. Lilly markets and sells teriparatide [rDNA origin] injection under the trade name Forteo®. Forteo® was approved by the FDA on November 26, 2002.

B. The '334 Patent

11. The '334 patent, titled "Medication Dispensing Apparatus with Spring-Driven Locking Feature Enabled by Administration of Final Dose," and assigned to Lilly, was duly and legally issued by the United States Patent and Trademark Office ("PTO") on April 14, 2009, from U.S. Patent Application No. 10/598,987, filed as PCT Application No. PCT/US2005/010206 on March 25, 2005. The '334 patent claims priority to U.S. Provisional Application No. 60/557,545, filed March 30, 2004, and U.S. Provisional Application No. 60/638,027, filed December 21, 2004. The '334 patent claims, *inter alia*, a medication dispensing apparatus comprising: a housing, a drive member within said housing movable in a distal direction; a fluid container defining a medicine-filled reservoir with a movable piston at one end and an outlet at the other end; a plunger element; a gear set including first and second pinions; a first rack; a second rack; and a latching element including a latching lip and a skid. The '334 patent is listed in the FDA publication titled

Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") in connection with Forteo®. A true and correct copy of the '334 patent is attached as ***Exhibit A***.

C. Radius's Supplemental NDA Submission to NDA No. 208743

12. Radius filed or caused to be filed with the FDA Radius's Supplemental NDA for Radius's Abaloparatide Injection USP, 80 mcg / 40 mcL under 21 U.S.C. § 355(b)(2) and seeks approval of Radius's Supplemental NDA in the United States before the expiration of the '334 patent.

13. Radius's Supplemental NDA contains a paragraph IV certification alleging that the claims of the '334 patent would not be infringed by Radius's Supplemental NDA.

14. Radius sent or caused to be sent to Lilly a Notice Letter dated May 27, 2021, notifying Lilly that Radius's Supplemental NDA includes a paragraph IV certification to FDA stating that Radius's Supplemental NDA does not infringe the claims of the '334 patent and providing information pursuant to 21 U.S.C. § 355(j)(2)(B).

15. The Notice Letter does not purport to include an Offer of Confidential Access to Lilly to review Radius's Supplemental NDA.

16. On June 7, 2021, outside counsel for Lilly requested detailed diagrams and, if detailed diagrams were not available, a sample of the injection device described in Radius's Supplemental NDA Submission. On June 15, 2021, outside counsel for Radius confirmed that two samples of the injection device described in Radius's Supplemental NDA Submission would be provided. On July 2, 2021, Lilly's outside counsel received a package with samples of the injection device described in Radius's Supplemental NDA submission. In light of the July 4th holiday and Lilly's closure through July 12, 2021, it is not feasible to complete an analysis of the samples and any detailed diagrams as needed prior to July 12, 2021.

17. On information and belief, the product described in Radius's Supplemental NDA is covered by one or more claims of the '334 patent.

18. On information and belief, Radius's Supplemental NDA constitutes infringement by Radius of the '334 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, or sale of the product described in Radius's Supplemental NDA would infringe the '334 patent under 35 U.S.C. § 271(a), (b), and/or (c).

19. Radius knows and intends that physicians will prescribe, and patients will take, Radius's product for which approval is sought in Radius's Supplemental NDA. Radius had knowledge of the '334 patent and, by its proposed product for which approval is sought in Radius's Supplemental NDA, knows or should know that it will aid and abet in another's direct infringement of at least one of the claims of the '334 patent.

20. An actual case or controversy exists between Lilly and Radius with respect to infringement of the '334 patent.

21. Lilly commenced this action within 45 days of receiving Radius's Notice Letter.

COUNT I FOR PATENT INFRINGEMENT
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 7,517,334)

22. Lilly incorporates by reference and realleges Paragraphs 1–21 above as though fully restated herein.

23. Pursuant to 35 U.S.C. § 271(e)(2), Radius's Supplemental NDA submission to the FDA is an act of infringement of at least one claim of the '334 patent by Radius.

24. If Radius's Supplemental NDA is approved by the FDA, Radius's commercial manufacture, use, or sale of the product described in Radius's Supplemental NDA would directly infringe, either literally or under the doctrine of equivalents, at least one claim of the '334 patent under 35 U.S.C. § 271.

COUNT II FOR PATENT INFRINGEMENT
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 7,517,334)

25. Lilly incorporates by reference and realleges Paragraphs 1–24 above as though fully restated herein.

26. Radius has knowledge of the '334 patent.

27. Upon FDA approval of Radius's Supplemental NDA, Radius will intentionally encourage acts of direct infringement of at least claim 1 of the '334 patent by others, with knowledge that their acts are encouraging infringement.

PRAYER FOR RELIEF

Wherefore, Lilly respectfully requests the following relief:

A. Under 35 U.S.C. § 271(e)(2)(A), a judgment that Radius has infringed U.S. Patent No. 7,517,334 by submitting its supplemental submission to NDA No. 208743 to the FDA seeking approval of its Supplemental NDA submission prior to expiration of U.S. Patent No. 7,517,334;

B. A judgment declaring that Radius's commercial manufacture, use, and/or sale of the product for which approval is sought in Radius's Supplemental NDA submission prior to expiration of U.S. Patent No. 7,517,334 would constitute infringement under 35 U.S.C. § 271(a) and/or (b);

C. A judgment and order that the effective date of any FDA approval of Radius's Supplemental NDA shall be no earlier than the expiration date of U.S. Patent No. 7,517,334 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. Entry of an injunction enjoining Radius, and all persons acting in concert with Radius, from seeking, obtaining, or maintaining approval of Radius's Supplemental NDA until the expiration of the patent in suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. An award of damages or other relief adequate to compensate Lilly for Radius's infringement of the '334 patent, including all pre-judgment and post-judgment interest at the maximum rate permitted by law;

F. Lilly is entitled to any further appropriate relief under 35 U.S.C. § 271(e)(4); and

G. Any further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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